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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/887,496	BANERJEE ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-21,23-38,40-64,69-74,78-83,87-89,93 and 99-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1,3-21,23-38,40-64,69-74,78-83,87-89,93,99-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the applicant's response filed on 02/22/2008, wherein claim 123 has been amended.

Applicant's amendment overcomes the objection to claim 123 made in the previous office action.

Claims 1, 3-21, 23-38, 40-64, 69-74, 78-83, 87-89, 93 and 99-146 are pending, and examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-21, 23-38, 40-64, 69-74, 78-83, 87-89, 99-112, 117-119, and 122-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainner et al. (US 6,150,418, PTO-892 of record) in view of Carling et al. (US 5,674,860, PTO-892 of record), and PDR.

Hochrainner et al. discloses propellant-free pharmaceutical composition comprising formoterol or its salt, or addition products (preferably, formeterol fumarate as salt, hydrate as addition product), a known bronchodilator, particularly stable on storage with concentration 10 –500 mg/ml (see col.1, lines 37-46, lines 65-67; col.2 lines 6-11),

in aqueous ethanol, and ethanol mixture (water and ethanol are well known polar and protic solvents, see col.2 lines 24-34), in the form of a solution or suspension for use in inhalers for nasal therapy, see abstract and claims 1-4, 8 in particular. Hochrainer et al. further teaches that the pharmaceutical composition is such that it can be administered by inhalation using a suitable nebuliser, see col.4, lines 19-20 and col. 5, lines 33-41. Hochrainer et al. teaches that the pH range is preferably between 2.0-7.0 and most preferably between 4.5-5.5. The employment of inorganic acids, and organic acids such as phosphoric acids, citric acid, tartaric acid, fumaric acid etc. and the employment of buffers in its composition are also taught, see in particular col.3, lines 35-40 and col.4 line 55 to col. 5, line 7; and inorganic salts, sodium chloride, and organic salts such as for example, sodium, potassium or ammonium salts of citric acid, Na-EDTA (see col.2 lines 56-64, col. 4, lines 55-57) in the composition is also taught. Hochrainer et al. teaches the concentration of formoterol to be between about 75 mg/ml and about 500 mg/ml, which may be used with diluent, and other ingredients for the preparation of therapeutical composition. See in particular claims 1-4. Hochrainer et al. also teaches that additional active ingredients such as steroids, antichlolinergics could be incorporated in its composition, see claim 19. It is taught that the pharmaceutical preparation suitable for administration is obtained by diluting the active substance concentrate with a pharmacologically suitable solvent. See column 4, lines 21-25. It is taught that the formulation for administration is obtained by diluting to 0.9 mg/ml of formoterol with the diluents such as water, aqueous saline and the PH is adjusted for stable storage. See column 4, lines 26-29; column 5, lines 1-6. A formulation containing

a solvent mixture of ethanol/water, formoterol in a concentration of about 0.9 to about 1.5 mg/ml adjusted to a pH of about 4.5 to about 5.5 is also disclosed. See column 8, claim 22. The pharmaceutical compositions therein can contain surfactants for stabilizing suspensions or other stabilizers which include sorbitan esters which reads on instant Polysorbate 80. See column 3, lines 10-27.

Hochrainer et al. also discloses a kit or an article of manufacture comprising the same combination and packaging material include containers, nebulizers. Preferred nebulizers include inhalers. See column 5, lines 33-47. The compositions therein are employed in the methods of treating obstructive respiratory diseases and asthma, see col. 1, lines 1- 37.

Hochrainer et al. does not teach particularly the employment of a steroidal anti-inflammatory agent, fluticasone propionate, and its concentration.

Hochrainer et al. does not explicitly teach the concentration of formoterol such as 5 μg/ml to about 200 μg/ml, 50 μg/ml to about 200 μg/ml, 59 μg/ml, 118 μg/ml in its pharmaceutical composition, and does not expressly teach the concentration of buffer providing particular PH value, and the ionic strength of the composition.

Carling et al. discloses a pharmaceutical composition comprising formoterol (free base) or formoterol fumarate salt in combination with corticosteroid anti-inflammatory agent, budesonide, in a pharmaceutically acceptable fluid such as a liquid (see col.4 line 2), by inhalation from a nebulizer (see col.3 line 51) for the treatment of respiratory disorders such as asthma (see title and abstract, col.1 lines 10-15, 46-67). Carling et al. also discloses the effective amount of formoterol, 6-100 μg, preferred 6-48 μg (the

instant claimed amount within the range of Carling et al.), in a pharmaceutical composition therein (see col.3 lines 44-45). Carling et al. also discloses that a pharmaceutical composition of the combination therein is formulated into a single dosage administration (see Example 1-3 at col.4). Carling et al. also discloses a kit or an article of manufacture comprising the same combination and a nebulizer (see col.3 line 8-10 and 50-52, claims 1-36). Carling et al. also discloses the employment of a tonicity adjusting agent herein such as salts of inorganic or organic salts, e.g., succinate, lactate (see col.3 lines 30-38) and adding oleic acid may improve the physical stability (see col.4 line 12-14).

PDR teaches fluticasone propionate as a known corticosteroid readily employed in the method of treating asthma.

From the teaching of PDR, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ fluticasone propionate in the composition of Hochrainer et al. It is prima facie obvious to combine two agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. The optimization of a result effective parameter, e.g., the effective amounts of active ingredients and excipients in a therapeutical dosage form, is considered within the skill of the artisan. See, In re Boesch and Slanev (CCPA) 204 USPQ 215. The skilled artisan would see a container as a vial useful for multiple uses, absent information the contrary.

It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as the concentration of formoterol in its

pharmaceutical composition, and the concentration of buffer providing particular PH value, and the ionic strength of the composition. The optimization of a result effective parameter, e.g., the effective amounts of active ingredients and excipients in a therapeutical dosage form, is considered within the skill of the artisan. See, In re Boesch and Slanev (CCPA) 204 USPQ 215.

With regard to the limitations "whereby the composition has an estimated shelf-life of greater than 1 month usage time at 25 °C and greater than or equal to 1 year storage time at 5 °C, "whereby greater than 90 % of the initial amount of formoterol in the composition remains at such time", and "the composition is formulated for direct administration", Hochrainer et al. disclose a formulation containing a solvent mixture of ethanol/water, formoterol in a concentration of about 0.9 to about 1.5 mg/ml adjusted to a pH of about 4.5 to about 5.5, and further teaches that the pharmaceutical preparation suitable for administration is obtained by diluting the active substance concentrate with with polar solvents such as water, aqueous saline and adjusting the PH to obtain a stable formulation. See column 8, claim 22. The compositions therein can contain steroids. Thus, absent showing unexpected, and significant benefit residing in the particular limitations herein, the claimed invention would have been obvious to one of skill in the art. Hochrainer et al. particularly teach that the concentrated solution may be used for making pharmaceutical composition which is such that it can be administered by inhalation using a suitable nebuliser, see col. 4, lines 19-20 and col. 5, lines 33-41. Therefore, it would have been obvious to make a diluted formoterol solution suitable for

direct administration. It is noted that fluticasone is not water soluble, therefore, a suspension of fluticasone would have been obvious to one of ordinary skill in the art.

Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainner et al. (US 6150418, PTO-892 of record) in view of Carling et al. (US 5674860, PTO-892 of record), and PDR, and further in view of PDR at pages 482, 535, 537, 2828 (of record).

The same disclosures of Hochrainner et al. in view Carling et al. (US 5674860), and PDR have been discussed in the 103(a) rejection set forth above.

Hochrainner et al., Carling et al. do not expressly disclose further adding one or more agent recited in claim 93 herein to the composition.

PDR teaches that albuterol (beta2-adrenoreceptor agonist), accolate (leukotriene receptor antagonist) and Zyflo (5-lipoxygenase inhibitor) are all known to be effective in treating asthma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a third active such as those enumerated immediately above in a combination composition along with formoterol and fluticasone.

One of ordinary skill in the art would have been motivated to employ a third active such as those enumerated immediately above in a combination composition along with formoterol and fluticasone because all three actives are known to be useful in treating asthma. Combining two agents which are known to be useful to treat asthma

individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Claims 113-116 and 120-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainner et al. (US 6150418, PTO-892 of record) in view of Carling et al. (US 5674860, PTO-892 of record), and PDR, and further in view of Hardman et al. (Goodman Gilman 's *The Pharmacological Basis of Therapeutics*,1996, page 665, of record) or Leckie et al (*Novel Therapy* Of COPD, abstract, Jan 2000, of record).

The same disclosures of Hochrainner et al. in view Carling et al. (US 5674860, and PDR have been discussed in the 103(a) rejection set forth above.

Hochrainner et al., Carling et al. and PDR do not expressly disclose further adding an anticholinergic agent such as ipratropium bromide or tiotropium bromide to the composition therein.

Hardman et al. teaches that ipratropium bromide is an anticholinergic agent useful in treating asthma.

Leckie et al teaches that tiotropium is a known bronchodilator employed in treatment of asthma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a third active such as ipratropium bromide or tiotropium bromide in a combination composition along with formoterol and fluticasone.

One of ordinary skill in the art would have been motivated to employ a third active such as ipratropium bromide or tiotropium bromide in a combination composition

along with formoterol and fluticasone because all three actives are known to be useful in treating asthma. Combining two agents which are known to be useful to treat asthma individually into a single composition useful for the very snme purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Claims 129-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainner et al. (US 6,150,418, PTO-892 of record), in view of Remington's Pharmaceutical Sciences, Seventeenth Edition, 1985, pages 1443, 1451.

Hochrainner et al. discloses propellant-free pharmaceutical composition comprising formoterol or its salt (preferably, formeterol fumarate), a known bronchodilator, particularly stable on storage with concentration 10 –500 mg/ml (see col.1 line 65-67; col.2 line 6-11), in aqueous ethanol, and ethanol mixture (water and ethanol are well known polar and protic solvents, see col.2 lines 24-34), in the form of a solution or suspension for use in inhalers for nasal therapy, see abstract and claims 1-4, 8 in particular. Hochrainer et al. further teaches that the pharmaceutical composition is such that it can be administered by inhalation using a suitable nebuliser, see col.4, lines 19-20 and col. 5, lines 33-41. Hochrainer et al. teaches that the pH range is preferably between 2.0-7.0 and most preferably between 4.5-5.5. The employment of inorganic acids, and organic acids such as phosphoric acids, citric acid, tartaric acid (i.e addition of tartaric acid to formoterol, results in instant formoterol tartrate), fumaric acid etc and the employment of buffers, e.g. phosphate buffers, in its composition are also taught, see in particular col.3, lines 35-40 and col.4 line 55 to col. 5, line 7; and inorganic salts,

sodium chloride, and organic salts such as for example, sodium, potassium or ammonium salts of citric acid (see col.2 lines 56-64) in the composition is also taught. Hochrainer et al. teaches the concentration of formoterol to be between about 75 mg/ml and about 500 mg/ml, which may be used with diluent, and other ingredients for the preparation of therapeutical composition. See in particular claims 1-4. Hochrainer et al. also teaches that additional active ingredients such as steroids, antichlolinergics could be incorporated in its composition, see claim 19. It is taught that the pharmaceutical preparation suitable for administration is obtained by diluting the active substance concentrate with a pharmacologically suitable solvent. See column 4, lines 21-25. It is taught that the formulation for administration is obtained by diluting to 0.9 mg/ml of formoterol with the diluents such as water, aqueous saline and the PH is adjusted for stable storage. See column 4, lines 26-29; column 5, lines 1-6. A formulation containing a solvent mixture of ethanol/water, formoterol in a concentration of about 0.9 to about 1.5 mg/ml adjusted to a pH of about 4.5 to about 5.5 is also disclosed. See column 8, claim 22.

Hochrainer et al. also discloses a kit or an article of manufacture comprising the same combination and packaging material which include containers, nebulizers. Preferred nebulizers include inhalers. See column 5, lines 33-50. The compositions therein are employed in the methods of treating obstructive respiratory diseases and asthma, see col. 1, lines 1- 37.

Hochrainer et al. does not explicitly teach the concentration of formoterol such as 5 μg/ml to about 200 μg/ml, in its pharmaceutical composition, and does not expressly teach the concentration of buffer providing particular PH value.

It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as the concentration of formoterol in its pharmaceutical composition, and the concentration of buffer providing particular PH value. The optimization of a result effective parameter, e.g., the effective amounts of active ingredients and excipients in a therapeutical dosage form, is considered within the skill of the artisan. See, In re Boesch and Slanev (CCPA) 204 USPQ 215. Note, sterility of a pharmaceutical composition is an essential element in the practice of pharmacy, and thus is deemed to be obvious. See Remington's Pharmaceutical Science, pages 1443, 1451 attached herein. Also, note that the skilled artisan would see a container as a vial useful for multiple uses, absent information the contrary.

With regard to the limitations "whereby the composition has an estimated shelf-life of greater than 1 month usage time at 25 °C and greater than or equal to 1 year storage time at 5 °C, "whereby greater than 90 % of the initial amount of formoterol in the composition remains at such time", and "the composition is formulated for direct administration", Hochrainer et al. disclose a formulation containing a solvent mixture of ethanol/water, formoterol in a concentration of about 0.9 to about 1.5 mg/ml adjusted to a pH of about 4.5 to about 5.5, and further teaches that the pharmaceutical preparation suitable for administration is obtained by diluting the active substance concentrate with with polar solvents such as water, aqueous saline and adjusting the PH to obtain a

stable formulation. See column 8, claim 22. The compositions therein can contain steroids. Thus, absent showing unexpected, and significant benefit residing in the particular limitation herein, the claimed invention would have been obvious to one of skill in the art. Hochrainer et al. particularly teach that the concentrated solution may be used for making pharmaceutical composition which is such that it can be administered by inhalation using a suitable nebuliser, see col. 4, lines 19-20 and col. 5, lines 33-41. Therefore, it would have been obvious to make a diluted formoterol solution suitable for direct administration. It is noted that fluticasone is not water soluble, therefore, a suspension of fluticasone would have been obvious to one of ordinary skill in the art.

Response to Arguments

Applicants' amendments and remarks have been fully considered, but are not found persuasive.

Applicant's remarks on issued patents have been considered. It is pointed out that the examiner will not make any comment on issued US patent. The evidence of record shows that the subject matter as claimed is a combination of known components selected for their known properties for treatment of obstructuve respiratory diseases and asthma. A claim which unites elements with no change in their respective functions to yield a predictable result is not patentable in the absence of secondary considerations. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

KSR Int'l v. Teleflex Inc., 82 USPQ2d 1385, 1395 (2007). As to the arguments about concentration, note, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955)

Applicant argues that "Carling does not teach dilute aqueous pharmaceutical compositions with formoterol in solution and steroid in suspension in water that is propellant-free, that are suitable for long-term storage and direct administration." These arguments have been considered, but not found persuasive. It is pointed out that Carling et al. was employed for its teachings that formoterol (free base) or formoterol fumarate salt is employed in combination with corticosteroid anti-inflammatory agent, budesonide, in a pharmaceutically acceptable fluid for the treatment of respiratory disorders such as asthma. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of invention to employ a steroidal anti-inflammatory agent in the composition taught by Hochrainer et al. It is prima facie obvious to combine two agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious.

Applicant argues that "PDR does not teach pharmaceutical compositions comprising formoterol in dilute solution and steroid in suspension, in propellant-free water, which is suitable for long term storage and direct administration." It is pointed out

that PDR was employed for its teachings that fluticasone propionate as a known corticosteroid readily employed in the method of treating asthma. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of invention to employ a steroidal anti-inflammatory agent, fluticasone propionate in the composition taught by Hochrainer et al. It is prima facie obvious to combine two agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious.

Applicant argues that "However, none of the references cited by the Examiner teach formoterol in solution and steroid in suspension, in propellant-free water." These arguments have been considered, but not found persuasive. As the combined teachings of the prior art renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the formoterol in solution and steroid in suspension in propellant-free water, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni,Ph.D
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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617